

Grip: gepersonaliseerde e-health voor het bevorderen van zelfmanagement vaardigheden van patiënten met somatisch onvoldoende verklaarde lichamelijke klachten

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28030

Source

NTR

Brief title

MYSelf

Health condition

Medically unexplained symptoms (In Dutch: SOLK)

Sponsors and support

Primary sponsor: University Medical Centre Groningen, the Netherlands

Source(s) of monetary or material Support: Zonmw, Onderzoeksprogramma GGZ middellang; project number: 636310005

Intervention

Outcome measures

Primary outcome

Physical health-related quality of life, as measured 16 weeks after baseline, using the RAND 36's physical component score.

Secondary outcome

Secondary outcomes are psychological functioning (RAND-36 mental component score), symptom severity (Somatization subscale of the 4DSQ + additional items), patient satisfaction (Client Satisfaction Questionnaire), health care utilization (iMCQ) and productivity loss (iPCQ).

Study description

Background summary

Background of the study: Medically Unexplained Symptoms (MUS) are physical symptoms that have existed for more than several weeks and for which adequate medical examination has not revealed any condition that sufficiently explains the symptoms. MUS lead to severe limitations in daily life, and to high direct and indirect costs. Since MUS initially are presented in primary care, it is important that GPs recognize and treat MUS at an early stage, to prevent the further development into chronic MUS. Early intervention in primary care is also important since the available evidence-based psychological treatments, such as cognitive behavioral therapy, are often not accepted by patients. Current guidelines therefore indicate that the GP has a central role in the care for MUS patients. However, GPs find it difficult to treat these patients. We developed an e-Health system, Master Your Symptoms (MYSelf), that supports general practitioners and their patients to work on improving self-management strategies for MUS. The development of such strategies has the potential to improve patients' quality of life, and to prevent the development of severe chronic MUS. In addition, Grip has the potential to reduce medical costs.

Objective of the study: Main objective: To assess the effectiveness of MYSelf in comparison to care as usual in improving quality of life and symptom severity. Secondary objectives: 1) To investigate which characteristics of primary care professionals (General Practitioners (GPs), and General practice mental health workers (GP-MHWs; In Dutch: POH-GGZ)) predict short- and longterm effectiveness of MYSelf; 2) To investigate which patient characteristics predict effectiveness of MYSelf; 3) To investigate the short- and longterm cost-effectiveness of MYSelf in comparison to care as usual; 4) To investigate which mechanism predicts treatment outcomes.

Study design: Pragmatic randomized controlled trial.

Study population: Primary care patients with mild to moderate MUS, aged 18 years and older. All participants will be recruited within the Netherlands.

Intervention: The research group participates in MYSelf, guided by the GP and GP mental health worker; the control group receives care as usual from the GP.

Primary study parameters/outcome of the study: The 16-week physical component score of the Dutch version of the RAND-36 (measure of health-related quality of life) will be used as our primary outcome.

Secondary study parameters/outcome of the study: Secondary outcomes are the RAND-36's Mental component score, symptom severity, psychological symptoms, health care utilization, and productivity loss.

Study objective

Main hypothesis: Master Your Symptoms is effective in improving the perceived physical health-related quality of life of patients with mild to moderate medically unexplained symptoms.

Secondary hypotheses:

- Master your Symptoms is cost-effective in treating patients with mild to moderate medically unexplained symptoms, compared to care as usual.
- Characteristics of primary care professionals (e.g. attitude towards e-health) moderate the effectiveness of Master Your Symptoms.
- Patient characteristics (e.g. type and severity of presented somatic symptoms) predict effectiveness of Master Your Symptoms.

Study design

Primary outcome: Physical health-related quality of life, as measured 16 weeks after baseline, using the RAND 36's physical component score.

Intervention

Intervention group receives Master Your Symptoms, a personalized self-help e-health intervention, guided by the GP and/or GP-mental health nurse.

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

1. Age \geq 18 years.
2. Presenting with mild to moderate medically unexplained symptoms, as defined by the guidelines provided by the Dutch College of General Practitioners: 'physical symptoms that have persisted for more than several weeks and for which adequate medical examination has not revealed any condition that sufficiently explains the symptoms' (Olde Hartman et al., 2013).
3. Main symptom concerns pain, gastro-intestinal complaints or fatigue.
4. Adequate command of the Dutch language, no major cognitive or visual impairment, according to the GP.
5. In possession of an e-mail account and a personal computer, laptop or tablet with internet connection.

Exclusion criteria

1. Referred to or currently treated by a mental health professional.
2. Start or adjusted dosage of psychotropic medication \leq 3 months ago.
3. Presence of severe anxiety, depression, or presence of post traumatic stress syndrome.
3. Pregnancy.
4. Engaged in a legal procedure concerning disability-related financial benefits.

Study design

Design

Study type: Interventional
Intervention model: Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-10-2018
Enrollment:	165
Type:	Anticipated

Ethics review

Positive opinion	
Date:	08-11-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register ID

NTR-new NL7390

NTR-old NTR7598

Other Registration number METc Groningen: Metc 2017/280 : ABR number:
NL61185.042.17

Study results